DEPARTMENT OF HEALTH & HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES
REGION IX

75 Hawthorne Street
Suite 408
San Francisco, CA 94105

JAN 2 3 2004

Hawaii (03-004)
Approved: 01/12/04
Effective: 10/01/03

Aileen Hiramatsu, Administrator
MedQUEST Division
Department of Human Services
P.O. Box 700190
Kapolei, HI 96707

Dear Ms. Hiramatsu:

On January 12, 2004, CMS approved Hawaii State Plan Amendment (SPA) 03-004 that provides for the use of a Medicaid supplemental rebate agreement (SRA) and preferred drug list. The SPA is effective October 1, 2003.

The HCFA Form 179 for this SPA, which we sent separately to you, inadvertently contained an older version of the Supplement to Attachment 3.1-A and 3.1-B pages 3.2 through 3.5. Enclosed are the correct versions with the appropriate approval and effective dates.

If you have any questions, please contact Cheryl Young at 415-744-3598 or via email at cyoung2@cms.hhs.gov.

Sincerely,

Linda Minamoto
Associate Regional Administrator
Division of Medicaid & Children's Health

Enclosure

cc: Claire Hardwick, CMSO
Susan Ruiz, DMCH

12a. Prescribed drugs must be listed in the Hawaii Medicaid Drug Formulary. All other prescribed drugs require prior authorization.

(1) Those drug products produced by manufacturers who have entered into and comply with an agreement under Section 1927(a) of the Act may be considered for payment by being listed in the Hawaii Medicaid Drug Formulary or may require prior authorization approval. Pursuant to 42 U.S.C. section 1396r-8 (d) (5), certain medications may require prior authorization. The following categories of drugs subject to restriction under 1927 are not covered:

(a) Used for cosmetic purposes or hair growth;

(b) With associated tests or monitoring purchased exclusively from the manufacturer or designee as a condition of sale;

(c) Which are classed as "less than effective" as described in Section 107(c)(3) of the Drug Amendments of 1962 or are identical, similar or related; and

(d) Used to promote fertility.

(2) The following drugs or classes of drugs, produced by manufacturers complying with Section 1927(a) of the Act, or their medical uses will be selectively covered as decided by the Advisory Medicaid Formulary Committee (the responsibilities for which have been delegated to the State Drug Use Review Board or the Pharmacy and Therapeutics Committee:

(a) Agents used for the symptomatic relief of cough and colds.

(b) Vitamins and minerals products except prenatal and fluoride preparations;

(c) Non-prescription drugs;

(d) Barbiturates;

(e) Benzodiazepines; and

(f) Agents used for anorexia or weight gain.

(3) Preferred Drug List (PDL) / Prior Authorization

Prior authorization may be established for high cost and/or highly utilized items to ensure products are being utilized appropriately. Additionally, certain designated therapeutic classes will be reviewed periodically to consider which products are clinically appropriate and most cost-effective. Those products within the therapeutic class that are not determined to be clinically superior and/or are not cost-effective will be prior authorized.

Pursuant to 42 U.S.C. section 1396r-8, the State will establish prior authorization for certain drugs, including a preferred drug list with prior authorization for drugs not included on the PDL. Prior authorization request will be responded to within 24-hour of receipt by telephone or other telecommunication; and in an emergency, a 72-hour supply of the drug desired by the prescribing physician will be allowed (an emergency is defined as a situation that exists when the withholding of medication chosen by the prescribing physician will cause the patient's medical condition to worsen or prevent improvement and the person designated to approve prior authorization is not available for approval by telephone or other means)..

The Department may maintain a Preferred Drug List containing the names of pharmaceutical drugs for which prior authorization will not be required under the medical assistance program. All other pharmaceutical drugs not on the Preferred Drug List, and determined by the Department to be in the same drug class and used for the treatment of the same medical condition as drug(s) placed on the Preferred Drug List, will require prior authorization. The Med-QUEST administrator may seek the recommendations of an

advisory committee to be comprised of medical and pharmaceutical professionals regarding the pharmaceutical drugs that may be placed on a Preferred Drug List.

The State will appoint a Pharmacy and Therapeutics (P&T) Committee consisting of physicians and pharmacists or utilize the Drug Utilization Review (DUR) board in accordance with federal law.

(4) Supplemental Drug Rebate Agreements:

The State is in compliance with section 1927 of the Social Security Act. The state will cover drugs of federal rebate participating manufacturers. The state is in compliance with reporting requirements for utilization and restrictions of coverage. Pharmaceutical manufacturers may audit utilization data. The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification.

The State will negotiate supplemental rebates in addition to the federal rebates provided for in Title XIX. Rebate agreements between the state and a pharmaceutical manufacturer will be separate from the federal rebates.

A rebate agreement between the State and a drug manufacturer for drugs provided to the Medicaid program, submitted to CMS on December 3, 2003 and entitled, State of Hawaii Supplemental Rebate Agreement, has been authorized by CMS.

Supplemental rebates received by the state in excess of those required under the national drug rebate program will be shared with the federal government on the same percentage basis as applied under the national drug rebate agreement.

All drugs covered by the program, irrespective of a supplemental rebate agreement, will comply with the provisions of the national drug rebate agreement.

(5) The maximum quantity of any medication to be paid equals the larger of a one month supply or one hundred units. The State may implement stricter quantity restrictions to help ensure proper utilization and reduce billing errors.

(6) In compliance with Section 1927(b)(2) of the Social Security Act, the fiscal agent is engaged to report to each manufacturer not later than sixty days after the end of each calendar quarter and in a form consistent with a standard reporting format established by the Secretary, information on the total number of dosage units of each covered outpatient drug dispensed under the plan during the quarter and shall promptly transmit a copy of such report to the Secretary as instructed by CMS.

12b. Partial dentures limited to fill the space due to the loss of one or more anterior teeth and to fill the space due to the loss of two or more posterior teeth exclusive of third molars. Temporary dentures allowed only when teeth have been extracted recently with prior authorization and subject to maximums or prosthetics.

Only one prosthetic appliances in any five year period is allowed for a maximum of one for each type, partial and full dentures, per arch per recipient; lifetime. This is allowed when present or previous dentures cannot be repaired or adjusted.

12c. Prosthetic devices require prior authorization when the cost of purchase, repair or manufacture exceeds $50.00.